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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	SenoRx Inc.
b. Company Address:	11 Columbia, Suite A
c. Telephone: Facsimile:	(949) 362-4800 (949) 362-3519
d. Contact Person:	Amy Boucly Director, Regulatory Affairs and Quality Assurance
e. Date Summary Prepared:	

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	SenoRx Biopsy Device SenoRx Driver SenoRx Control Module SenoRxVacuum System
b. Classification Name:	Biopsy Device, 876.1075

3. IDENTIFICATION OF PREDICATE DEVICES

Mammotome® Biopsy System	Ethicon Endo-Surgery (K991980, K003297)
Easy Guide™ Electrosurgical Access Device	SenoRx Inc. (K012004)

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4. DESCRIPTION OF THE DEVICE

The SenoRx Biopsy Device is a percutaneous electrosurgical biopsy device which is indicated for use in providing breast tissue samples for diagnostic sampling of breast abnormalities under ultrasound guidance.

5. STATEMENT OF INTENDED USE

The SenoRx Biopsy Device System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

6. COMPARISON WITH PREDICATE DEVICES

The intended use, design, construction, materials and technology are comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Ms. Amy Boucly
Director, Regulatory Affairs
and Quality Assurance
SenoRx, Inc.
11 Columbia, Suite A
Aliso Viejo, California 92656

Re: K013641
Trade/Device Name: SenoRx Biopsy Device
Regulation Number: 878.4400, 876.1075
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: GEI, KNW
Dated: October 30, 2001
Received: November 5, 2001

Dear Ms. Boucly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 FDA Indications for Use Page

510(k) number (if known): K013641

Device Name: **SenoRx Biopsy Device**

Indications for Use:

The SenoRx Biopsy Device System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013641